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7

8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
10 OAKLAND DIVISION
11

12 KIM CHANNING on behalf of herself as
an heir at law of ELGA IDA HINDIN and
13 as Executor of the Estate and/or Successor
in Interest of ELGA IDA HINDIN;
14 JENNIFER LYNN RICHARDS;
JEFFREY PAUL HINDIN and
15 GERALDINE G. HINDIN,

16 Plaintiffs,

17 v.

18 JOHNSON & JOHNSON; ORTHO-
MCNEIL PHARMACEUTICAL, INC.;
19 JOHNSON & JOHNSON
PHARMACEUTICAL RESEARCH
20 DEVELOPMENT, LLC,

21 Defendants.
22

Case No. CV 08 2913 SBA

**ANSWER OF JOHNSON & JOHNSON TO
PLAINTIFFS' WRONGFUL DEATH
COMPLAINT AND JURY DEMAND**

23 Defendant Johnson & Johnson ("J&J") hereby answers Plaintiff's Wrongful Death
24 Complaint and Jury Demand ("Plaintiffs' Complaint") as follows:

25 Defendant denies each and every allegation, statement, matter and thing contained in
26 Plaintiffs' Complaint except as is hereinafter expressly admitted or alleged. Defendant Johnson
27 & Johnson specifically denies each and every allegation of acts or omissions as to it, as Johnson
28

1 & Johnson did not develop, test, research or market levofloxacin at any time, and Plaintiff's
2 Complaint asserts no recognizable cause of action against this defendant.

3 **INTRODUCTION**

4 1. Defendant admits that levofloxacin is a fluoroquinolone, but denies the remaining
5 allegations in paragraph 1 of Plaintiffs' Complaint.

6 2. Defendant admits that Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known
7 as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), marketed levofloxacin in the United
8 States until December 31, 2007, when all assets of OMP were transferred to OMJPI, which now
9 markets levofloxacin in the United States, but denies the remaining allegations in paragraph 2 of
10 Plaintiffs' Complaint.

11 3. Defendant admits that levofloxacin was approved by the FDA for its labeled uses,
12 but denies the remaining allegations in paragraph 3 of Plaintiffs' Complaint.

13 4. Defendant denies the allegations in paragraph 4 of Plaintiffs' Complaint.

14 5. Defendant denies the allegations in paragraph 5 of Plaintiffs' Complaint.

15 6. Defendant is without knowledge or information sufficient to admit or deny the
16 allegations that Elga Ida Hindin took Levaquin®, but otherwise denies the allegations in
17 paragraph 6 of Plaintiffs' Complaint

18 7. Defendant states that paragraph 7 of the Complaint requires no response as the
19 Complaint speaks for itself, but to the extent a response is required, it denies the allegations in
20 paragraph 7 of Plaintiffs' Complaint.

21 **JURISDICTION**

22 8. Defendant admits the allegations in paragraph 8 of Plaintiffs' Complaint.

23 9. Defendant admits the allegations in paragraph 9 of Plaintiffs' Complaint.

24 10. Defendant is without knowledge or information sufficient to admit or deny the
25 allegations in paragraph 10 of Plaintiffs' Complaint.

26 11. Defendant is without knowledge or information sufficient to admit or deny the
27 allegations in paragraph 11 of Plaintiffs' Complaint.

28 12. Defendant is without knowledge or information sufficient to admit or deny the

1 allegations in paragraph 12 of Plaintiffs' Complaint.

2 13. Defendant is without knowledge or information sufficient to admit or deny the
3 allegations in paragraph 13 of Plaintiffs' Complaint.

4 14. Defendant admits the allegations in paragraph 14 of Plaintiffs' Complaint.

5 15. Defendant denies the allegations in paragraph 15 of Plaintiffs' Complaint as stated.
6 Defendant states that OMJPI is a Pennsylvania corporation with its principal place of business in
7 Titusville, New Jersey.

8 16. Defendant denies the allegations in paragraph 16 of Plaintiffs' Complaint, except
9 to admit that Johnson & Johnson Pharmaceutical Research & Development, LLC ("J&JPRD")
10 did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP,
11 now known as OMJPI, and is now a product of OMJPI.

12 17. Defendant denies the allegations in paragraph 17 of Plaintiffs' Complaint as stated.

13 **FACTS**

14 18. In response to the allegations in paragraph 18 of Plaintiffs' Complaint, Defendant
15 denies the allegations as stated as incomplete, and states that levofloxacin is a synthetic broad
16 spectrum antibacterial agent for oral and intravenous administration. The approved uses of
17 Levaquin® are stated in the prescribing information in the package insert. Defendant did not
18 manufacture or market Levaquin® at any time.

19 19. Defendant denies the allegations in paragraph 19 of Plaintiffs' Complaint.

20 20. Defendant denies the allegations in paragraph 20 of Plaintiffs' Complaint.

21 21. Defendant denies the allegations in paragraph 21 of Plaintiffs' Complaint, as
22 stated, but admits that different fluoroquinolones may differ in safety profile.

23 22. Defendant denies the allegations in paragraph 22 of Plaintiffs' Complaint.
24 Defendant did not manufacture or market Levaquin® at any time.

25 23. In response to the allegations in paragraph 23 of Plaintiffs' Complaint, Defendant
26 admits that Levaquin® was developed by Daiichi, that it has a licensing agreement with Daiichi,
27 that OMP, now known as OMJPI, manufactured and marketed and now OMJPI manufactures and
28 markets Levaquin® pursuant to a licensing agreement, but denies the remaining allegations of

1 paragraph 23 of Plaintiffs' Complaint.

2 24. Defendant denies the allegations in paragraph 24 of Plaintiffs' Complaint.

3 25. Defendant denies the allegations in paragraph 25 of Plaintiffs' Complaint.

4 26. Defendant is without knowledge or information sufficient to admit or deny the
5 allegations in paragraph 26 of Plaintiffs' Complaint.

6 27. Defendant denies the allegations in paragraph 27 of Plaintiffs' Complaint as stated.
7 The chemical composition of Levofloxacin is stated in the prescribing information in the package
8 insert.

9 28. Defendant denies the allegations in paragraph 28 of Plaintiffs' Complaint.

10 29. Defendant denies the allegations in paragraph 29 of Plaintiffs' Complaint.

11 30. Defendant denies the allegations in paragraph 30 of Plaintiffs' Complaint as stated.
12 The allegations are an incomplete description of the scientific knowledge regarding
13 fluoroquinolones. Defendant states that the scientific literature and studies regarding
14 fluoroquinolones speak for themselves. Defendant further states that the scientific literature and
15 reported research on Levaquin® form part of the basis of the marketing of the drug and the
16 approval of it by the FDA, pursuant to the prescribing information.

17 31. Defendant denies the allegations in paragraph 31 of Plaintiffs' Complaint as stated.
18 The allegations are an incomplete description of the scientific knowledge regarding
19 fluoroquinolones. Defendant states that the scientific literature and studies regarding
20 fluoroquinolones speak for themselves. Defendant further states that the scientific literature and
21 reported research on Levaquin® form part of the basis of the marketing of the drug and the
22 approval of it by the FDA, pursuant to the prescribing information.

23 32. Defendant denies the allegations in paragraph 32 of Plaintiffs' Complaint.

24 33. Defendant denies the allegations in paragraph 33 of Plaintiffs' Complaint.

25 34. Defendant denies the allegations in paragraph 34 of Plaintiffs' Complaint,
26 including each and every subparagraph (a) through (gg).

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING

35. In response to the allegations in paragraph 35 of Plaintiffs' Complaint, Defendant restates, realleges and incorporates by reference paragraphs 1 through 34 of its answer to Plaintiffs' Complaint.

36. Defendant denies the allegations in paragraph 36 of Plaintiffs' Complaint, except to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

37. Defendant denies the allegations in paragraph 37 of Plaintiffs' Complaint as stated.

38. Defendant denies the allegations in paragraph 38 of Plaintiffs' Complaint.

39. In response to the allegations in paragraph 39 of Plaintiffs' Complaint, Defendant is without sufficient information to admit or deny the allegation that Elga Ida Hindin used Levaquin® in the manner for which it was intended, and therefore denies the same. Defendant denies the remaining allegations in paragraph 39 of Plaintiffs' Complaint.

40. Defendant denies the allegations in paragraph 40 of Plaintiffs' Complaint.

41. In response to the allegations in paragraph 41 of Plaintiffs' Complaint, Defendant is without sufficient information to admit or deny the allegation that Elga Ida Hindin used Levaquin® in the manner for which it was intended, and therefore denies the same. Defendant denies the remaining allegations in paragraph 41 of Plaintiffs' Complaint.

42. Defendant denies the allegations in paragraph 42 of Plaintiffs' Complaint.

43. Defendant denies the allegations in paragraph 43 of Plaintiffs' Complaint.

44. Defendant denies the allegations in paragraph 44 of Plaintiffs' Complaint.

45. Defendant denies the allegations in paragraph 45 of Plaintiffs' Complaint.

46. Defendant denies the allegations in paragraph 46 of Plaintiffs' Complaint.

47. Defendant denies the allegations in paragraph 47 of Plaintiffs' Complaint.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

48. In response to the allegations in paragraph 48 of Plaintiffs' Complaint, Defendant

1 restates, realleges and incorporates by reference paragraphs 1 through 47 of its answer to
2 Plaintiffs' Complaint.

3 49. Defendant denies the allegations in paragraph 49 of Plaintiffs' Complaint, except
4 to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin®
5 was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

6 50. Defendant denies the allegations in paragraph 50 of Plaintiffs' Complaint.

7 51. Defendant denies the allegations in paragraph 51 of Plaintiffs' Complaint.

8 52. Defendant denies the allegations in paragraph 52 of Plaintiffs' Complaint.

9 **THIRD CAUSE OF ACTION**
10 **STRICT PRODUCTS LIABILITY -DEFECT DUE TO INADEQUATE WARNING**

11 53. In response to the allegations in paragraph 53 of Plaintiffs' Complaint, Defendant
12 restates, realleges and incorporates by reference paragraphs 1 through 52 of its answer to
13 Plaintiffs' Complaint.

14 54. Defendant denies the allegations in paragraph 54 of Plaintiffs' Complaint, except
15 to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin®
16 was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

17 55. Defendant denies the allegations in paragraph 55 of Plaintiffs' Complaint.

18 56. Defendant denies the allegations in paragraph 56 of Plaintiffs' Complaint.

19 57. Defendant denies the allegations in paragraph 57 of Plaintiffs' Complaint.

20 58. Defendant denies the allegations in paragraph 58 of Plaintiffs' Complaint.

21 **FOURTH CAUSE OF ACTION**
22 **NEGLIGENCE**

23 59. In response to the allegations in paragraph 59 of Plaintiffs' Complaint, Defendant
24 restates, realleges and incorporates by reference paragraphs 1 through 59 of its answer to
25 Plaintiffs' Complaint.

26 60. Defendant states that it was subject only to those duties imposed by applicable
27 law, and denies the allegations of paragraph 60 of Plaintiffs' Complaint. Defendant denies that
28 Levaquin® was defective or dangerous.

1 61. Defendant denies the allegations in paragraph 61 of Plaintiffs' Complaint.

2 62. Defendant denies the allegations in paragraph 62 of Plaintiffs' Complaint.

3 63. Defendant denies the allegations in paragraph 63 of Plaintiffs' Complaint.

4 64. Defendant denies the allegations in paragraph 64 of Plaintiffs' Complaint.

5 65. Defendant denies the allegations in paragraph 65 of Plaintiffs' Complaint.

6 **FIFTH CAUSE OF ACTION**
7 **BREACH OF EXPRESS WARRANTY**

8 66. In response to the allegations in paragraph 66 of Plaintiffs' Complaint, Defendant
9 restates, realleges and incorporates by reference paragraphs 1 through 65 of its answer to
10 Plaintiffs' Complaint.

11 67. Defendant denies the allegations in paragraph 67 of Plaintiffs' Complaint.

12 68. Defendant denies the allegations in paragraph 68 of Plaintiffs' Complaint.

13 69. Defendant denies the allegations in paragraph 69 of Plaintiffs' Complaint and
14 denies that it extended any express warranties to Plaintiffs.

15 **SIXTH CAUSE OF ACTION**
16 **BREACH OF IMPLIED WARRANTY**

17 70. In response to the allegations in paragraph 70 of Plaintiffs' Complaint, Defendant
18 restates and incorporates by reference paragraphs 1 through 69 of its answer to Plaintiffs'
19 Complaint.

20 71. Defendant denies the allegations in paragraph 71 of Plaintiffs' Complaint, except
21 to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin®
22 was a product of OMP, now known as OMJPI, and is now a product of OMJPI. Answering
23 further, Defendant states that the allegations contained therein call for a legal conclusion to which
24 no response is necessary, but responding further, Defendant denies those allegations to the extent
25 they seek to impose obligations on Defendant beyond those required by law.

26 72. In response to the allegations in paragraph 72 of Plaintiffs' Complaint, Defendant
27 is without sufficient information to admit or deny the allegations of this paragraph and therefore
28 denies the same.

1 73. Defendant denies the allegations in paragraph 73 of Plaintiffs' Complaint.

2 74. Defendant denies the allegations in paragraph 74 of Plaintiffs' Complaint, and
3 denies that it breached any warranties, if any, extended by operation of law.

4 **SEVENTH CAUSE OF ACTION**
5 **NEGLIGENT MISREPRESENTATION**

6 75. In response to the allegations in paragraph 75 of Plaintiffs' Complaint, Defendant
7 restates and incorporates by reference paragraphs 1 through 75 of its answer to Plaintiffs'
8 Complaint.

9 76. Defendant denies the allegations in paragraph 76 of Plaintiffs' Complaint.

10 77. Defendant denies the allegations in paragraph 77 of Plaintiffs' Complaint.

11 78. In response to the allegations in paragraph 78 of Plaintiffs' Complaint, Defendant
12 is without sufficient information to admit or deny the allegations of this paragraph and therefore
13 denies the same.

14 79. Defendant denies the allegations in paragraph 79 of Plaintiffs' Complaint.

15 **EIGHTH CAUSE OF ACTION**
16 **FRAUD**

17 80. In response to the allegations in paragraph 80 of Plaintiffs' Complaint, Defendant
18 restates and incorporates by reference paragraphs 1 through 79 of its answer to Plaintiffs'
19 Complaint.

20 81. Defendant denies the allegations in paragraph 81 of Plaintiffs' Complaint.

21 82. Defendant denies the allegations in paragraph 82 of Plaintiffs' Complaint and
22 states that serious as well as minor side effects, including tendon rupture, have been reported in
23 conjunction with use of all quinolones, including Levaquin®. Defendant further states that the
24 FDA-approved prescribing information for Levaquin® has at all times contained the appropriate
25 information for the prescribing physician.

26 83. Defendant denies the allegations in paragraph 83 of Plaintiffs' Complaint.

27 84. Defendant denies the allegations in paragraph 84 of Plaintiffs' Complaint,
28 including each and every subparagraph (a) through (j).

85. Defendant denies the allegations in paragraph 85 of Plaintiffs' Complaint.
86. Defendant denies the allegations in paragraph 86 of Plaintiffs' Complaint.
87. Defendant denies the allegations in paragraph 87 of Plaintiffs' Complaint.
88. Defendant denies the allegations in paragraph 88 of Plaintiffs' Complaint.
89. Defendant denies the allegations in paragraph 89 of Plaintiffs' Complaint.
90. Defendant denies the allegations in paragraph 90 of Plaintiffs' Complaint.
91. Defendant denies the allegations in paragraph 91 of Plaintiffs' Complaint.
92. Defendant denies the allegations in paragraph 92 of Plaintiffs' Complaint.
93. Defendant denies the allegations in paragraph 93 of Plaintiffs' Complaint.
94. Defendant denies the allegations in paragraph 94 of Plaintiffs' Complaint.
95. Defendant denies the allegations in paragraph 95 of Plaintiffs' Complaint.
96. Defendant denies the allegations in paragraph 96 of Plaintiffs' Complaint.
97. Defendant denies the allegations in paragraph 97 of Plaintiffs' Complaint.
98. Defendant denies the allegations in paragraph 98 of Plaintiffs' Complaint.
99. Defendant denies the allegations in paragraph 99 of Plaintiffs' Complaint.
100. Defendant denies the allegations in paragraph 100 of Plaintiffs' Complaint.
101. Defendant denies the allegations in paragraph 101 of Plaintiffs' Complaint.

AFFIRMATIVE DEFENSES

AS FURTHER AND SEPARATE AFFIRMATIVE DEFENSES, the answering Defendant alleges as to Plaintiffs:

FIRST AFFIRMATIVE RELIEF

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE RELIEF

Plaintiffs' claims are barred by the applicable statute of limitations.

THIRD AFFIRMATIVE RELIEF

Any purported injuries of which Plaintiffs complain in the Complaint were not caused by Defendant, but were caused by the actions or inactions of a person or persons or entities over whom Defendant had neither control nor right of control. Plaintiffs' recovery should be barred

1 or, at a minimum, should be reduced or apportioned in accordance with the principles of
2 comparative negligence and the Joint Tortfeasor Contribution Act.

3 **FOURTH AFFIRMATIVE RELIEF**

4 Plaintiffs' alleged damages or injuries, if any, were caused in whole or in part by the
5 Decedent's unreasonable, unforeseeable, inappropriate, and/or improper use of the product.

6 **FIFTH AFFIRMATIVE RELIEF**

7 Plaintiffs have failed to mitigate damages, if any.

8 **SIXTH AFFIRMATIVE RELIEF**

9 The products identified in the Complaint were approved by the FDA and other
10 government authorities and this answering Defendant acted at all times in compliance with the
11 rules and regulations of the FDA and other governmental authorities.

12 **SEVENTH AFFIRMATIVE RELIEF**

13 Levaquin® (levofloxacin) is a prescription medical product. It falls under the auspices of
14 the Food, Drug, and Cosmetic Act and regulations promulgated by the federal Food and Drug
15 Administration, and all causes of action are therefore preempted by Federal Law. See 21 U.S.C.
16 §§ 301 to 399, 71 Fed. Reg. 3922 (January 24, 2006). Plaintiffs' cause of actions against
17 Defendant related to Levaquin® (levofloxacin), therefore, fail to state a claim upon which relief
18 can be granted; such claim, if allowed, would conflict with applicable federal law and violate the
19 Supremacy Clause of the United States Constitution.

20 **EIGHTH AFFIRMATIVE RELIEF**

21 The products identified in the Complaint were in conformity with the state of the art
22 and/or the state of scientific knowledge at the relevant times involved.

23 **NINTH AFFIRMATIVE RELIEF**

24 Plaintiffs' claims are barred because the benefits relevant to the product outweighed the
25 risks.

26 **TENTH AFFIRMATIVE RELIEF**

27 Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.
28

ELEVENTH AFFIRMATIVE RELIEF

Plaintiffs' claims are barred by the learned intermediary doctrine.

TWELFTH AFFIRMATIVE RELIEF

Plaintiffs' claims are barred by the Decedent's assumption of the risk.

THIRTEENTH AFFIRMATIVE RELIEF

Plaintiffs' claims are barred by the doctrine of laches and/or estoppel.

FOURTEENTH AFFIRMATIVE RELIEF

Plaintiffs' injuries are the result of a superseding cause.

FIFTEENTH AFFIRMATIVE RELIEF

Plaintiffs have failed to allege fraud, concealment, or misrepresentation with sufficient particularity.

SIXTEENTH AFFIRMATIVE RELIEF

No privity of contract existed between Plaintiffs and this answering Defendant.

SEVENTEENTH AFFIRMATIVE RELIEF

Affirmatively and alternatively, this Defendant pleads the application of Comment (k) to the Restatement of Torts (Second) Section 402A and Restatement (Third) Torts; Products Liability Section 6.

EIGHTEENTH AFFIRMATIVE RELIEF

To the extent not stated above, Defendant raises all affirmative defenses available under the law of the forum in which each respective claim arose.

NINETEENTH AFFIRMATIVE RELIEF

This Defendant specifically reserves the right to present other and further defenses after further discovery and investigation herein.

WHEREFORE, Defendant prays that Plaintiffs take nothing by way of their Complaint, and that judgment for costs, reasonable attorneys' fees, and such other relief as the Court may deem proper be awarded to Defendant.

1 Dated: August 22, 2008

Respectfully submitted,

2 DRINKER BIDDLE & REATH LLP

3
4 By: /s/ John J. Powers

5 JOHN J. POWERS (SBN 145623)

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10 Attorneys for Defendant

11 JOHNSON & JOHNSON

12 **DEMAND FOR JURY TRIAL**

13 Defendant demands trial by jury of all issues triable by a jury pursuant to Federal Rule of
14 Civil Procedure 38 and Civil Local Rule 3-6.

15 Dated: August 22, 2008

Respectfully submitted,

16 DRINKER BIDDLE & REATH LLP

17
18 By: /s/ John J. Powers

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